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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,977	12/12/2001	Kin-Ping Wong	AN 2002.00	4934

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McCutchen Doyle Brown & Enersen LLP
Three Embarcadero Center, Suite 1800
San Francisco, CA 94111-4067

EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,977

Applicant(s)

WONG, KIN-PING

Examiner

Susan D. Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004 and 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 and 21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 3 is/are allowed.
- 6) ☒ Claim(s) 1,4-6,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 23, 2004 has been entered.
2. Claims 1-21 are currently pending.
3. In Paper No. 7, dated November 18, 2002, applicant elected with traverse of Group I, claims 1-6 and 19-21, and cancer for species A.
4. Claims 7-18 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
5. Claims 1-6, 19, and 20 are examined on the merits solely in regards to the elected species of cancer.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of pathological cell growth in mice, does not reasonably provide enablement for treatment of cancer. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition which has the ability to treat cancer in any host. Human is a host that is considered encompassed by applicant's claims. It is well established in the art that the types of cancer are widely varied and can be extremely difficult to treat. Applicant's specification shows a study with rats that uses the claimed composition to reduce the growth of pathological cells. The specification also shows *in vitro* inhibition of the proliferation of cells. It is well known in the art that animal models and *in vitro* results are not considered to be enabling for human treatment. For example, Gura (Science (1997), vol. 278, pp. 1041-1041), Dermer (Biotechnology (1994), vol. 12, pp. 320) and Gorman (Time (May 18, 1998), vol. 151, no. 19, pp. 38-44) each discuss that animal and *in vitro* cancer models are not necessarily predictive of the results that would be seen in humans. Due to this unpredictability in the art, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if the claimed composition would be able to function against cancer as claimed. This undue experimentation shows that applicant's specification is not enabled for using the claimed composition to treat cancer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1, 4-6, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,294,526 in light of US Pat. Pub. No. 2004/0126437 as evidence of qualities inherent in US '526.

US '526 teaches isolating apigenin from *Scutellaria barbata*. Apigenin is isolated by extracting the plant in a solvent, filtering the solvent, and extracting the filtrate to obtain apigenin (see paragraph spanning columns 3 and 4). While US '526 does not mention the optical absorbance of apigenin; US '437 shows that apigenin shows absorbance at 280 nm (see Fig. 4 and paragraph [0031]). Therefore, US '526 teaches isolating a fraction from *S. barbata* that has an optical absorbance between 260 and 330 nm. US '526 also teaches combining the apigenin with compounds that are considered to be immunostimulatory.

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8. Claims 1, 4-6, 19, and 20 are rejected. Claims 2 and 3 are considered allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Susan D. Coe, Examiner
July 20, 2004